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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): LIFT-030/00US

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Application Number	Filed
09/787,368	March 14, 2001

First Named Inventor: Chenicheri Hariharan NAIR et al.

Art Unit	Examiner
1753	Arun S. PHASGE

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant/inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [XX] attorney or agent of record. Registration number 44,541
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

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November 20, 2006
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

[ ] *Total of _____ forms are submitted.

PATENT
Attorney Docket No. LIFT-030/00US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Chenicheri Hariharan NAIR *et al.*.

Application No.: **09/787,368**

Confirmation No.: **2783**

Filed: **March 14, 2001**

Group Art Unit: **1753**

For: **PURIFICATION OF BLOOD CLOTTING PROTEINS**

Examiner: **Arun S. PHASGE**

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PRE-APPEAL BRIEF REQUEST FOR REVIEW

In response to the Final Official Action of May 18, 2006, and the Advisory Action issued October 12, 2006, Applicants respectfully request reconsideration in view of the following Remarks.

Remarks begin at page 2 of this paper.

REMARKS

I. Rejection of the Claims under 35 U.S.C.§ 103(a)

The claims stand rejected under 35 U.S.C. § 103(a) as obvious over the combination of *Laustsen* (U.S. 5,437,774), *Gritzner* (U.S. 4,043,895) and *Margolis* (U.S. 5,650,055). The Examiner argues that *Gritzner*, "shows the precipitation of the fibrinogen outside the [electrophoresis] cell" and thereby concludes that *Gritzner* "shows that before precipitation the fibrinogen would be dissolved within the solution and thus would meet the claimed invention."[1]

Applicants respectfully submit that that the combination of *Laustsen*, *Gritzner*, and *Margolis* fails to support a *prima facie* case of obviousness because this combination "fails to teach or suggest all the claim limitations".

A. Independent Method Claims

Independent method claims 16, 24, and 32 each recite a step (e) of "*recovering a solution* comprising the at least one blood clotting protein" (emphasis added). Thus, the claimed methods require a discrete step in which a *solution* comprising at least one blood clotting protein is "recovered" -- *i.e.*, regained or reclaimed from the mixture.

The Examiner states that "the reference [*i.e.*, *Laustsen*] fails to disclose the use of the electrophoretic separation of the blood clotting proteins, such as fibrinogen"[2], and that *Margolis* is only cited for its teaching regarding "the reversal of polarity to obtain the desired purity of macromolecule".[3] Thus, both *Laustsen* and *Margolis* fail to describe a step of recovering a solution comprising at least one blood clotting protein.

Instead, the Examiner relies on the statement in *Gritzner* that "protein *precipitation* (generally fibrinogen) takes place *outside* the [electrophoresis] cell" (emphasis added).[4] However, *Gritzner* fails to state or imply that the precipitated fibrinogen is *recovered* (as distinguished, *e.g.*, from being *discarded*). Furthermore, even if, *arguendo*, the "precipitated" fibrinogen of *Gritzner* was deemed "recovered", it is clearly not recovered in the form of a *solution* as required in the claimed invention, but rather as a solid.

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[1] Office Action of May 18, 2006, page 2, fifth paragraph
2 Office Action of August 26, 2005, page 5, lines 6-8
3 *Ibid.*, page 5, lines 14-15
[4] *Gritzner* at col. 9, line 5-9

As indicated above, the Examiner states that "before precipitation the fibrinogen would be dissolved within the solution".[5] Accordingly, Applicants believe that the Examiner may be arguing that a solution of fibrinogen is *inherently* present prior to precipitation of fibrinogen. However, even if a solution of fibrinogen were disclosed by *Gritzner* (which Applicants do not concede for the reasons stated below), there is still no suggestion in *Gritzner* that a fibrinogen solution is *recovered*, as in the claimed method.

In order for *Gritzner* to inherently describe a solution of fibrinogen, such a solution must "necessarily" be present.[6] However, *Gritzner* itself suggests that fibrinogen is not necessarily present in the form of a solution prior to precipitation. *Gritzner* is directed to an "electrophoretic apparatus useful for continuous separation of *colloidal suspensions* and solutions" (emphasis added).[7] Thus, before precipitation, the fibrinogen is not necessarily present in the form of a solution as it could also be present in the form of a colloidal *suspension* – particularly in view of the known poor solubility of fibrinogen.[8]

Furthermore, the Examiner has failed to point out where the applied references describe a multi-step method according to claim 24 which includes additional purification steps (f)-(i).

Thus, the combination of *Laustsen*, *Gritzner* and *Margolis* fails to teach (a) *recovery* of a blood clotting protein, wherein (b) the recovered blood clotting protein is in the form of a *solution*. Accordingly, the combination of *Laustsen*, *Gritzner* and *Margolis* fails to teach or suggest all of the claim limitations, and therefore fails to support a *prima facie* case of obviousness.

Since the Examiner has failed to support a *prima facie* case of obviousness for the independent method claims, the Examiner has also necessarily failed to support a *prima facie* case of obviousness for the method claims which depend therefrom.

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5 Office Action of May 18, 2006 at page 2, paragraph 5.

[6] MPEP 2112 IV: "the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherent sea of that result or characteristic". "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'"

[7] *E.g.*, col. 1, lines 45-48

[8] *E.g.*, present specification at page 1, lines 18-22

B. Independent "System" Claim 39

Claim 39 is directed to a system which has means for applying at least one selected electric potential whereby the application of the electric potential "causes migration of at least one blood clotting proteins substantially *through* the first selective membrane" (emphasis added).

As indicated above, neither *Laustsen* nor *Margolis* describe the separation of a blood clotting proteins, and thus fail to describe an apparatus for separating a blood clotting protein.

Gritzner describes an apparatus in which stream A designates the "starting solution", and components which migrate through the semipermeable membrane enter solution B.[9] *Gritzner* specifically states that precipitated fibrinogen is obtained "on the holding of the output A stream".[10] Thus, *Gritzner* describes an apparatus configured so that fibrinogen remains in the "output A stream" and thus does not migrate *through* the semipermeable membrane as required by pending claim 39. Accordingly, the combination of *Laustsen*, *Gritzner* and *Margolis* fails to teach or suggest all of the limitations of claim 39, and thus this combination of references fails to support a *prima facie* case of obviousness.

For the same reason the combined references also fail to support a *prima facie* case of obviousness in regard to pending claim 40, which depends from claim 39.

C. "Isolated Fibrinogen" Claims 44 and 51

Pending claims 44 and 51 are directed to isolated fibrinogen prepared by the claimed methods (*i.e.* claims 16 and 48).

Claims 44 and 51 stand rejected under 35 U.S.C. 103(a) over the combination of *Laustsen*, *Gritzner*, and *Margolis*.[11] However, the arguments presented to-date by the Examiner have been directed to the method claims, not to "isolated fibrinogen". Accordingly, the Examiner has failed to provide any evidence or reasoning – whatsoever -- to support the rejection of claims 44 and 51 under 35 U.S.C. 103(a).

Moreover, Applicants note that claims 44 and 51 are directed to isolated fibrinogen made by the methods of claims 16 and 48, respectively. As discussed above, the Examiner has failed to support a *prima facie* case of obviousness in regard to the method claims.

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9 *Gritzner*, col. 2, lines 48-61
[10] *ibid.*, col. 9, line 7
[11] Office Action of August 26, 2005, Office Action of May 18, 2006, and Advisory Action of October 12, 2006.

Accordingly, the arguments presented by the Examiner in regard to the method claims would also fail to support a *prima facie* case of obviousness in regard to claims 44 and 51, particularly in view of the teaching of the present specification that fibrinogen prepared by the claimed method has quite different properties compared to conventionally isolated fibrinogen.[12]

Applicants also note that pending claim 51 was added as a new claim in the Response filed on February 24, 2006. However, in the Office Action of May 18, 2006, the Examiner failed to present any rejection of claim 51, or provide any arguments in regard to the patentability (or lack thereof) of pending claim 51. Thus, the Examiner has provided absolutely no reasoning on the record to support the rejection of claim 51.[13]

Accordingly, and for the reasons stated above, Applicants respectfully request that the rejection be withdrawn, and submit that the present application is now in condition for allowance. Early notification thereof is earnestly solicited.

Except for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or to credit any overpayment to Deposit Account No. 50-0310. This paragraph is intended to be a **constructive petition for extension of time** in accordance with 37 C.F.R. 1.136(a)(3).

Respectfully submitted,

Dated: November 20, 2006

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The obviousness-type double patenting rejection was obviated by the filing of a Terminal Disclaimer.
[12] See Applicants Response of September 18, 2006 at page 14, last paragraph
[13] The rejection of claim 51 was first presented in the Advisory Action of October 12, 2006